

3.0 SCHEDULES OF EVENTS

3.1 VACCINE

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This can be extended up to -56 days only if an additional procedure is needed to establish that the patient is melanoma-free prior to randomization

History/Physical Exam, Vital Signs, Performance Status, Routine Labs, Chest X-Ray q2 months in year 2, q3 months in year 3, then q6 months through year 5; CT or MRI at 18, 24, and 36 months (chest x-ray omitted if CT/MRI scheduled)

0.1 mL of a 1:10 dilution of Tice BCG (Tice-A) mixed with vaccine adjuvant and 0.1 mL of a 1:100 dilution of Tice BCG/TiceB1 mixed with vaccine adjuvant.

This can be extended up to -34 days if an additional procedure is needed to establish that the patient is melanoma-free prior to 0.1 mL of a 1:1000 dilution of Tice BCG (Tice-C) mixed with vaccine.

Randomization
Routine Labs: hematology (CBC with differential, platelet count), BUN or creatinine, LDH, SGOT, alkaline phosphatase, electrolytes
End of Treatment Month

Figure 1